No. 85-619

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS, INC.,
Petitioner,

v.

LARRY JAMES CHRISTOPHER THOMPSON and DONNA LYNN THOMPSON as Next Friends and Guardians of JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRISTOPHER THOMPSON, Individually, and DONNA LYNN THOMPSON, Individually, *et al.*,
Respondents.

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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STATEMENT OF THE CASE

This case arises on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit filed by petitioner Merrell Dow Pharmaceuticals, Inc. (hereinafter referred to as Merrell Dow). Merrell Dow is a pharmaceutical manufacturer incorporated in Delaware with its principal place of business in Hamilton County, Ohio (Petioner's Ap-

pendix at 13a, 23a).[1] Respondents are parents and children who are citizens and residents of the United Kingdom and Canada (Pet. App. at 13a, 23a).

Respondents originally filed their complaints in the Court of Common Pleas of Hamilton County, Ohio (Pet. App. at 12a, 23a). The gravamen of the complaints is that the children were born with multiple deformities as a result of their mother's ingestion of the drug Bendectin, which was developed, tested, promoted, manufactured and sold by Merrell Dow for the relief of nausea during pregnancy (Pet. App. at 13a, 23a). At all times relevant hereto, the development, testing, promotion and manufacture of Bendectin either took place in Hamilton County, Ohio, or was directed from Hamilton County, Ohio.

Each complaint consists of six causes of action, all of which are predicated on traditional state-created theories of tort liability, namely, negligence, strict liability, breach of warranty, fraud and misrepresentation. The fourth causes of action in the complaints allege that Merrell Dow violated specific provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321, *et seq.* (hereinafter FDCA), and that the violation of the federal statute "constitutes a rebuttable presumption of negligence" (Pet. App. at 16a, 26a).

Pursuant to 28 U.S.C. § 1441, petitioner removed the actions to the district court where they were consolidated with several hundred other cases. Respondents moved to remand the actions to state court pursuant to 28 U.S.C. § 1447(c) on the grounds that the claims do not provide a basis for federal question jurisdiction under 28 U.S.C. § 1331 and that removal

[1] Hereinafter referred to as "Pet. App."

on the basis of diversity of citizenship was prohibited by 28 U.S.C. § 1441(b), because petitioner is a citizen of Ohio (Respondents' Appendix at 1a-9a) (herein after referred to as "Resp. App.").

The district court denied respendents' motion to remand on the ground that the fourth causes of action of respondents' complaints arise under the laws of the United States and granted petitioner's motion to dismiss the actions on the ground of *forum non conveniens* (Pet. App. at 5a, 7a).

Respondents appealed and the United States Court of Appeals for the Sixth Circuit reversed and remanded the cases to the district court with instructions to remand them to state court. The Court of Appeals based its decision in part on this Court's holding in *Franchise Tax Board* v. *Construction Laborers Vacation Trust,* 463 U.S. 1 (1983) (hereinafter referred to as *"Franchise Tax Board"*), which it quoted as follows:

> Under our interpretations, Congress has given the lower courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a well-pleaded complaint establishes either that federal law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law.

(Pet. App. at 2a, 3a).

The Court of Appeals found federal law does not create respondents' fourth causes of action because, as the parties agree, the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the FDCA. It further found

that respondents' causes of action referred to the FDCA merely as one available criterion for determining whether petitioner was negligent and, therefore, respondents' right to relief did not necessarily depend on resolution of a substantial question of federal law. Based upon these findings, the Sixth Circuit held that the causes of action did not arise under federal law and were improperly removed to federal court (Pet. App. at 3a).

ARGUMENT

I. There Is No Conflict Between The Decision Of The Circuit Court And This Court's Decision In *Franchise Tax Board*

Petitioner alleges at length that there is a conflict between the circuit court's decision in this case and this Court's opinion in the case of *Franchise Tax Board* v. *Construction Laborers' Vacation Trust,* 463 U.S. 1 (1983). This assertion flows from a strained reading of the *Franchise Tax Board* case and a misunderstanding of the circuit court's holding.

In *Franchise Tax Board,* this Court set forth the criteria for determining if a case arises under the laws of the United States, thereby making exercise of federal jurisdiction appropriate. In doing so, this Court utilized a two-pronged test as follows:

> Under our interpretations, Congress has given the lower federal courts jurisdiction to hear, originally or by removal from a state court, only those cases in which a *well-pleaded* complaint establishes either that *federal law creates the cause of action* or that the plaintiff's right to relief necessarily depends on resolution of a *substantial question of federal law.*

Id. at 2856 (emphasis added).

Therefore, one of two threshold requirements must be met before a federal court may exercise jurisdiction over a state common law action, absent any other basis for jurisdiction. These threshold requirements are a well-pleaded complaint which establishes either that (a) federal law creates a cause of action or (b) plaintiff's right to relief necessarily depends on a substantial question of federal law. Neither basis for the exercise of federal jurisdiction is present in the instant case.

A. The FDCA does not create a private cause of action

Petitioner admits that the FDCA does not create a private cause of action.[2] It could not do otherwise for the legislative history of the FDCA makes it clear that Congress considered creating private causes of action prior to enacting the FDCA, but expressly refrained from doing so.[3]

Thus, unlike the ERISA Act considered by this Court in the *Franchise Tax Board* case, which provided for private suits by certain enumerated parties, Congress specifically considered creating private actions under the FDCA, but decided *not* to do so.

Nevertheless, petitioner has attempted to sidestep the clear legislative history of the FDCA and asserts,

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[2] In the case at bar, it was uncontested that the Federal Food, Drug and Cosmetic Act does not provide a private right of action for its violation (footnote omitted). Thus, federal law does not "create" the cause of action.

Petition for Writ of Certiorari, p. 7.

[3] *See Hearings on S. 1944 Before a Subcommittee of the Commerce,* U.S. Senate, 73rd Cong., 2d Sess. 10, 114, 219, 403, 431, 444 (1933).

albeit obliquely, that there is an implied right of action under the FDCA. This argument is equally specious.

If federal law expressly creates a remedy, federal subject matter jurisdiction will almost always be found. *See, e.g., Feibelman* v. *Packard,* 109 U.S. 421 (1883).

If a federal law creates a duty without creating a corresponding remedy, the court must determine whether a federal remedy can be implied from the duty so as to confer federal question jurisdiction. *See Cort* v. *Ash,* 422 U.S. 66 (1975); *Jackson Transit Authority* v. *Local Division 1285, Amalgamated Transit Union,* 457 U.S. 15 (1982).

The FDCA does not create a private right of action, and the courts have uniformly refused to imply a corresponding monetary remedy for individuals injured as a result of the breach of duty prescribed by the FDCA. *National Women's Health Network, Inc.* v. *A. H. Robbins, Inc.,* 545 F.Supp. 1177, 1179 (D.Mass. 1982); *Gelley* v. *Astra Pharmaceutical Products, Inc.,* 466 F.Supp. 182, 186 (D.Minn. 1979), *aff'd* 610 F.2d 558 (8th Cir. 1979); *Pacific Trading Company* v. *Wilson & Co., Inc.,* 547 F.2d 367 (7th Cir. 1976); *State of Florida ex rel. Broward County* v. *Eli Lilly & Co.,* 329 F.Supp. 364 (S.D. Fla. 1971); *Cross* v. *Board of Supervisors of San Mateo County,* 326 F.Supp. 634, 638 (N.D.Cal. 1968), *aff'd* 442 F.2d 362 (9th Cir. 1971); *Clairol, Inc.* v. *Suburban Cosmetics and Beauty Supply, Inc.,* 278 F.Supp. 859 (N.D.Ill. 1968).

The standards for determining the availability of an implied right of action were articulated by this Court in *Cort* v. *Ash,* 422 U.S. at 78, and recently reiterated

in *Jackson Transit Authority,* 457 U.S. at 21-24.[4] In *Jackson,* the union sued the Transit Authority in federal district court for breach of a collective bargaining agreement on the ground that the district court had federal jurisdiction on the theory that Section 13(c) of the Urban Mass Transportation Act, 49 U.S.C. § 1609 (c), required that the Transit Authority guarantee the preservation of the transit workers' collective bargaining rights. This Court framed the issue as "whether Congress intended such contract actions to set forth federal, rather than state, claims," *Id.* at 21, and counseled that the process for determining the intent of Congress should begin with an analysis of the "language of the statute itself." *Id.* at 24. The Court found that neither the statute itself nor its legislative history demonstrated that Congress intended to create federal causes of action for breaches of the contracts and that, therefore, Congress intended the contracts "to be governed by state law applied in state courts." *Id.* at 29.

Applying the standards articulated by the Supreme Court for determining the availability of an implied right of action, federal courts have examined the language of the FDCA itself and the legislative history of the FDCA to discern whether Congress intended to provide a monetary remedy to a private person injured as a result of violations of the FDCA. *National Women's Health Network, Inc.* v. *A. H. Robbins, Inc.,* 545 F.Supp. at 1179-80; *State of Florida ex rel. Bro-*

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[4] *See also Nieto-Santos* v. *Fletcher Farms,* No. 83-2119 (9th Cir. July 3, 1984) (also applying the standards articulated by this Court in *Cort* v. *Ash,* 422 U.S. at 78, for determining the availability of an implied right of action, held that the contract did not arise under federal law.

ward County v. *Eli Lilly & Co.*, 329 F.Supp. at 365. Section 307 of the FDCA provides that "all" proceedings for the enforcement of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337. Moreover, examination of the legislative history of the Act reveals that an express provision for a private right of action for damages was included in an early version of the Act, but was omitted from all later versions on the ground that it would create unnecessary federal action duplicative of state remedies. *Id.* at 365; *National Women's Health Network, Inc.* v. *A. H. Robbins, Inc.*, 545 F.Supp. at 1179.

Thus, federal courts considering the relationship between the FDCA and applicable state remedies have held that a violation of the FDCA is not an independent basis for federal question jurisdiction. *Id.* at 1178; *Gelley* v. *Astra Pharmaceutical Products, Inc.*, 466 F.Supp. at 187; *State of Florida ex rel. Broward County* v. *Eli Lilly & Co.*, 329 F.Supp. at 365-66; *Orthopedic Equipment Co.* v. *Eutsler*, 276 F.2d 455 (4th Cir. 1960); *Herman* v. *Smith, Klein and French Laboratories*, 286 F.Supp. 694 (E.D.Wis. 1968). In granting defendant's motion to dismiss plaintiff's action for lack of subject matter jurisdiction, the court in *Gelley* v. *Astra Pharmaceutical Products, Inc.*, held as follows:

> The Courts have uniformly rejected the argument that violations of the Food, Drug and Cosmetic Act provide a civil remedy to a private individual injured as a result of the violation[s]. . . . This court agrees with these decisions and therefore holds that the Food, Drug and Cosmetic Act does not by implication provide a monetary remedy to a private person injured as a result of a violation of the act. *Cort* v. *Ash*, 422 U.S. 66, 95 S.Ct. 2080, 45 L.E.2d 26 (1975).

> As there exists no private cause of action for a violation of the Act, there is no federal question jurisdiction. . . . As the parties are not diverse, it necessarily follows that this action must be dismissed for lack of subject matter jurisdiction.

466 F.Supp. at 186-87, *aff'd* 610 F.2d 558 (citations omitted). Respondents submit that this holding reflects the intent of Congress as evidenced in the legislative history of the FDCA.

The federal decisions referenced above are based on the premise that "a suit arises under the law that creates the cause of action." *American Wellworks* v. *Layne and Bowler Co.*, 241 U.S. 257, 260 (1916). This definition by Justice Holmes is entrenched in the history of the term "arising under." In accord with this rationale, in 1976 a New York federal court observed that where federal law does not replace rights granted by state law, "it is illogical to say that the litigant's claim is really predicated on a body of law which grants him no rights." *State of New York* v. *Local 1115 Joint Board, Nursing Home Hospital Employees Division*, 412 F.Supp. 720, 723 (E.D.N.Y. 1976). Since it is well-established that the FDCA does not create a private right of action for damages, it is "illogical" to say that respondents' fourth causes of action arise under the FDCA. Respondents' fourth causes of action are predicated on the Ohio law by way of paragraph 26 (Pet. App. at 17a, 27a). Applying the rationale of Justice Holmes, it necessarily follows that these negligence, product liability and contract actions arise under state law and should be heard in state court.

Therefore, there is no real conflict between the circuit court's decision and the first test of the appro-

priateness of removal. There is no private cause of action under the FDCA. Congress did not intend that there be private causes of action and courts have uniformly found that no private causes of action were implied. Hence, the petition for certiorari must fail unless respondents' right to relief necessarily depends on a *substantial* question of federal law.

B. No substantial question of federal law exists

In the instant cases, the respondents have alleged a violation of a federal safety statute, the FDCA, which, under the law of the state of Ohio, can give rise to legal liability. The common law of the state of Ohio, as in most states, has replaced the standard of care of the reasonable man with that of a safety statute where such a statute exists. Petitioner has not alleged that it was not subject to the FDCA, or that the FDCA is unconstitutional, or that the Ohio court's adoption of the FDCA, as evidence of the standard of care, is somehow violative of some legally protected right of petitioner. Petitioner only alleges that respondents, by their fourth causes of action, seek extra-territorial application of the FDCA. This defense is without merit. Respondents allege that the conduct of petitioner upon which the fourth causes of action is based occurred in Ohio and not only violates the laws of the United States but also the Ohio Pure Food and Drug Law as well.[5]

Indeed, the Ohio Law prohibits the manufacture of any drug which is misbranded[6] or which is sold with

[5] OHIO REV. CODE ANN. § 3715.01, *et seq.*

[6] OHIO REV. CODE ANN. § 3715.52(A).

false and misleading advertising.[7] The strictures of the Ohio Law are very similar to the FDCA.[8] Therefore, it is for an Ohio court to choose the standard it will utilize in determining legal culpability.

It, therefore, cannot be said that it is essential for the success of the respondents' actions that they be obliged to establish both the correctness and the applicability to their cases of the proposition of federal law. The Ohio Law furnishes an alternative basis for liability which an Ohio court is required to judicially notice.

In *Franchise Tax Board,* this Court stated as follows:

> . . . Leading commentators have suggested that for purposes of § 1331 an action "arises under" federal law "if in order for the plaintiff to secure relief sought he will be obliged to establish both the correctness and the applicability to his case of a proposition of federal law." P. Bator, P. Mishkin, D. Shapiro, & H. Wechsler, Hart and Wechsler's The Federal Courts and the Federal System 889 (2d ed. 1973). . . .

Id. at 9. Nothing of the sort exists here. There is nothing which is absolutely essential to the respondents' cases embodied in the FDCA that is not embodied to some extent in the Ohio Law.

In short, not every remote question of the applicability of federal law rises to the dignity of a substantial

[7] OHIO REV. CODE ANN. § 3715.52(E).

[8] See OHIO REV. CODE ANN. § 3715.64 (Misbranded drug) and § 3715.68 (False advertising) (Resp. App. at 10a) and compare these sections with 21 U.S.C. § 352.

federal question calling for the unique abilities of a federal court to decide it.

For example, in *Jacobson* v. *New York, N.H. & H.R. Co.*, 206 F.2d 153 (1st Cir. 1953), *aff'd* 347 U.S. 909 (1954), a passenger on defendant's train filed an action brought on the theory of negligence in federal district court. The passenger's amended complaint alleged that jurisdiction was based on the existence of a question under the Federal Safety Appliance Acts, 45 U.S.C.A. §§ 1, *et seq.* On review of the district court's dismissal for lack of federal subject matter jurisdiction, the First Circuit held that the cause of action invoking the Safety Appliance Acts was not within the jurisdiction of the court under 28 U.S.C. § 1331. *Id.* at 158.

The First Circuit observed that Congress did not create a statutory right of action in favor of passengers injured as a result of violations of the Safety Appliance Acts. It noted, however, that the courts may create a right of action on the principles of the common law by regarding the breach of a penal statute as an operative fact upon which common law tort liability may be predicated, if a person injured as a result of the breach "was within the class for whose protection the penal statute was presumably passed." *Id.*. at 156. The court further noted that it is "abundantly clear" that the federal courts have not, as a matter of federal common law, developed a private right of action for damages for personal injuries sustained by persons not entitled to sue under the provisions of the Federal Employers' Liability Act, 45 U.S.C. §§ 51, *et seq.* (1908), as a result of a breach of the Safety Appliance Acts. *Id.* at 157.

The court then considered the various common law principles developed by the states:

> . . . The courts of the various states differ extensively in their formulation and application of the common law principle upon which a liability is created in favor of a person injured by breach of a criminal statute. Some courts speak of the breach as "negligence *per se*", others as "evidence of negligence" or as "prima facie evidence of negligence." Nor are they completely in agreement as to what is meant by these phrases.

Id. at 156. Thus, the court concluded that "[w]here there is no diversity of citizenship such an action cannot be maintained in a federal district court, since the liability for damages and the corresponding private right of action, if any, are created by state law" (citations omitted). *Id.* at 157.*

The Supreme Court applied the same rationale in *Crane* v. *Cedar Rapid & Iowa City Railway Co.*, 395 U.S. 164 (1969), a suit also brought by a passenger of a railroad for injuries sustained. This Court held that the Safety Appliance Acts do not create a federal cause of action for nonemployees of a carrier and, therefore, "[t]he "nonemployee must look for his remedy to a common law action in tort, which is to say he must sue in state court, in the absence of diversity, to implement a state cause of action" (citations omitted). *Id.* at 166.

Both *Jacobson* and *Crane* relied heavily on the leading Supreme Court case of *Moore* v. *Chesapeake & O. Ry. Co.*, 291 U.S. 205 (1934). All three cases considered

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* If a plaintiff cannot maintain a private right of action under the FDCA, it is equally obvious that the fact that plaintiffs anticipate defenses in their complaints based on federal law does not give rise to federal court jurisdiction. *Franchise Tax Board*, 463 U.S. at 10.

the relationship between a federal safety statute and state law theories of negligence and, thus, closely parallel the case at bar.

In *Moore,* the Supreme Court held that a claim invoking a federal safety statute but brought under state law does not arise under federal law. *Id.* at 21. The case was brought by an employee of the defendant railroad for injuries sustained in the course of his employment with the railroad. The first paragraph of the *Moore* complaint alleged injuries sustained while he was in interstate commerce and was brought under the Federal Employers' Liability Act, 45 U.S.C. §§ 51, *et seq.* (1908), and the Federal Safety Appliance Acts, 45 U.S.C. §§ 1, *et seq.* (1885). This Court found that these allegations set forth a federal cause of action because, under the Federal Employers' Liability Act, in connection with the Safety Appliance Acts, an employee has a private right of action. *Id.* at 210-11.

The second paragraph of the *Moore* complaint alleged the same injuries as alleged in the first paragraph, but it stated that the injuries were sustained in intrastate commerce. Although this claim invoked the Federal Safety Appliance Acts, it was brought under the Employers' Liability Act of Kentucky which prescribed the liability of common carriers for negligently causing injuries to employees while engaged in intrastate commerce. The Kentucky statute provided that an employee should not be held guilty of contributory negligence or assumption of risk where a common carrier's violation of a state *or federal* statute, enacted for the safety of employees, contributed to the injury or death of the employee. As to the second count of the *Moore* complaint, this Court noted:

> [T]he second count of the complaint, in invoking the Federal Safety Appliance Acts, while declaring on the Kentucky Employers' Liability Act, cannot be regarded as setting up a claim which lay outside the purview of the state statute. . . . [A] violation of the acts for the safety of employees was to constitute negligence *per se* in applying the state statute and was to furnish the ground for precluding the defense of contributory negligence as well as that of assumption of risk.

Id. at 213. Thus, this Court held that an action brought under a state statute which brings within its scope "a breach of the duty imposed by the federal statute" is not "a suit arising under the laws of the United States." *Id.* at 214. The Court reasoned that "[t]he Federal Safety Appliance Acts, while prescribing absolute duties, and thus creating correlative rights in favor of injured employees, did not attempt to lay down rules governing actions for enforcing these rights." *Id.* at 215. In its final analysis, this Court contended that the Federal Safety Appliance Acts prescribed the duty of the carrier, but the right of the injured employee to recover damages sustained through the breach of the duty "sprang from the principles of the common law." *Id.* at 215.

In *State of Florida ex rel. Broward County* v. *Eli Lilly & Co.,* the district court dismissed an action brought by the state on its own behalf and on the behalf of consumers who sought monetary damages under the FDCA. Applying the standards articulated in *Moore* and its progeny, the court held the following:

> There is no need to decide whether under Florida law violation of the [Federal Food, Drug and Cosmetic] Act constitutes negligence *per se,* for absent diversity a complaint that alleges common law

> theories of recovery based upon the violation of a duty owed under a federal statute must be brought in a State court. *Jacobson* v. *New York, N.H. & H.R.R.*, 206 F.2d 153 (1st Cir. 1953), *aff'd* 347 U.S. 909, 74 S.Ct. 474 (1954); *Anderson* v. *Bingham & G. Ry.*, 169 F.2d 328 (10th Cir. 1948); 1 MOORE FEDERAL PRACTICE ¶ 0.60 [8.-3] (pp. 633-34).

329 F.Supp. at 366 n. 3.

The provisions of the FDCA prescribe the duties of a drug manufacturer engaged in interstate commerce but create no corresponding private right of action for damages under the FDCA. In their fourth causes of action, respondents have alleged that petitioner's violations of the FDCA constitute a rebuttable presumption of negligence. Respondents' claims invoke a federal safety act, but their right to recover damages, sustained through petitioner's alleged breach of duty, stems solely from Ohio common law principles. Thus, their claims are in fact and in substance indistinguishable from the claims brought in *Moore* and *Crane*. In relying on these Supreme Court decisions, the federal courts have uniformly refused to find federal question jurisdiction where private actions allege violations of the FDCA. Therefore, respondents are entitled to have their causes determined by the forum they originally selected.

CONCLUSION

There is no right of action created under the Federal Food, Drug and Cosmetic Act. There is no substantial question of federal law which is essential to the success of respondents' claim. Therefore, the petition for certiorari is specious and should be denied and respondents should be awarded their costs and reasonable attorneys' fees associated with opposing a frivolous petition.

Respectfully submitted,

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APPENDIX

APPENDIX A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Civil Action No. A-8307057

NEIL FRAZER MACTAVISH, *et al.*,

– and –

LARRY JAMES CHRISTOPHER THOMPSON, *et al.*,
Plaintiffs,

v.

MERRELL-DOW PHARMACEUTICALS, INC.,
Defendants.

PLAINTIFFS' MOTION TO REMAND UNDER § 1447(c) FOR LACK OF JURISDICTION

[Filed Oct. 14, 1983]

COME NOW the plaintiffs, by counsel, and on the basis more fully explained in the accompanying Memorandum in Support hereof, move this Court for an order remanding the above-captioned actions to the Court of Common Pleas for Hamilton County, Ohio.

Respectfully submitted,

WAITE, SCHNEIDER, BAYLESS & CHESLEY

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

Civil Action No. A-8307057

Neil Frazer Mactavish, *et al.*,

– and –

Larry James Christopher Thompson, *et al.*,
Plaintiffs,

v.

Merrell-Dow Pharmaceuticals, Inc.,
Defendants.

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO REMAND UNDER § 1447(c) FOR LACK OF JURISDICTION

I. Procedural History

Plaintiffs, residents of Scotland, filed the subject actions on September 1, 1983, in the Court of Common Pleas in Hamilton County, Ohio. On or about September 7, 1983, defendant filed a removal petition in this Court with the requisite bond. Plaintiffs, through this motion, seek an order under 28 U.S.C. § 1447(c) remanding the actions to the state court and requiring the defendants to pay plaintiffs, in accordance with 28 U.S.C. § 1446, costs and disbursements incurred by reason of the removal proceedings.

II. Operative Facts

Plaintiffs are residents of Scotland, United Kingdom, who allege that their children suffered birth defects as the result of the ingestion of Debendox during pregnancy. Debendox is the British trade name for the antinauseant morning sickness drug Bendectin manufactured by defendant Merrell. Plaintiffs allege, *inter alia*, that defendant

Merrell violated certain provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301-*et seq.* (52 Stat. 1040-*et seq.*)[1]

In their Fourth Cause of Action, plaintiffs allege that defendant violated 21 U.S.C. § 352 when it sold Debendox (a/k/a Bendectin) in a branded and defective condition. Plaintiffs allege in paragraph 26 of their complaints that Merrell's violation of the Food, Drug and Cosmetic Act in promoting of Debendox constituted a rebuttable presumption of negligence.[2]

Defendants suggest that by asserting violations of the Food, Drug and Cosmetic Act, plaintiffs' claims arise under the laws of the United States, and thereby give this Court original jurisdiction under 28 U.S.C. § 1331 and provide the basis for removal under 28 U.S.C. § 1441(b).

III. Issues Presented

A. *Do plaintiffs' claims arise under the laws of the United States in the sense of 28 U.S.C. § 1331?*

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[1] Case numbers are A83-07057 and A83-07058. Copies of the complaints are attached hereto and incorporated herewith by reference to defendant's removal petition (Exhibit A).

[2] Under Ohio law, violation of a safety statute is negligence *per se*, rendering the actor liable to plaintiff if his negligence caused or contributed to causing the plaintiff's injury. Plaintiffs will amend their complaint to include this allegation.

See Freeman v. *United States*, 509 F.2d 626 (6th Cir. 1975), in which the court held that when an injury is caused by an action which violates a safety statute, which is of the kind that the statute was intended to prevent, the action constitutes negligence *per se*.

See also Shroades v. *Rental Homes, Inc.*, 68 Ohio St.2d 20, 427 N.E.2d 774 (1981); *Zehe* v. *Falkner*, 26 Ohio St.2d 258, 271 N.E.2d 276 (1972). Both of these cases make clear that in Ohio it is a well-settled principle of law that a violation of a specific safety statute constitutes negligence *per se*.

B. *Are there any other legally cognizable grounds for removal?*

C. *Should the cases be removed?*

IV. Discussion

A. *Allegations made in plaintiff's complaints do not provide a basis for federal question jurisdiction under 28 U.S.C. § 1331.*

In asking the Court to recognize the Food, Drug and Cosmetic Act as establishing the standing of care required of a drug manufacturer, federal jurisdiction is not vested in this Court under 28 U.S.C. § 1331. In the instant case, unlike *Cort* v. *Ash*, 422 U.S. 66 (1975) (private right of action principles set forth by Court) plaintiffs do not assert a federal statute as the jurisdictional basis for their claims, nor do they assert that their claims arise under the federal Food, Drug and Cosmetic Act.

Moreover, it is clear that the Act does not create a private right of action. In fact, defendant has argued in open court that there is no private right of action:

> MR. LEECH: Your Honor, because there's no private right of action under the statute they are citing, and the cases so hold you can't recover damages as an individual plaintiff for the violation of the statute. The only person that can bring an action for violation of this statute is the U.S. Attorney's office.
>
> THE COURT: What statute?
>
> MR. LEECH: The Federal Drug & Cosmetic Act, and the section on which the plaintiff relies, regardless what they prove, they can't recover under the statute as a separate cause of action.

Oxendine v. *Richardson-Merrell, Inc.*, No. 1245-82 (Superior Ct., District of Columbia, Transcript May 2, 1983, pp. 147-48) (Exhibit B).

Similarly, in the *Koller* case, defendant argued that there was no private right of action under the Food, Drug and Cosmetic Act. Defendant wrote in its Memorandum in Support of Partial Summary Judgment:

> Moreover, the law is clear that there is no private cause of action under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq. See, e.g., Pacific Trading Co.* v. *Wilson and Co.*, 547 F.2d 367, 368 (7th Cir. 1976); *Orthopedic Equipment Co.* v. *Eustler*, 276 F.2d 455, 460 (4th Cir. 1960); *Keil* v. *Eli Lilly & Co.*, 490 F.Supp. 479 (E.D.Mich. 1980); *Gelley* v. *Astra Pharmaceutical Products, Inc.*, 466 F.Supp. 182, 186-187 (D. Minn. 1979), *aff'd* 610 F.2d 558 (9th Cir. 1979); *State of Florida ex rel. Broward County* v. *Eli Lilly & Co.*, 329 F. Supp. 364, 365-366 (S.D.Fla. 1971); *Cross* v. *Board of Supervisors of San Mateo County*, 326 F. Supp. 634, 638 (N.D.Cal. 1968); *aff'd* 442 F.2d 362 (9th Cir. 1971); *Clairol, Inc.* v. *Suburban Cosmetics and Beauty Supply, Inc.*, 278 F.Supp. 859, 860-861 (N.D.Ill. 1968).

Koller, et al. v. *Richardson-Merrell, Inc.*, No. 80-1258 (U.S. District Court for the District of Columbia, Memorandum of Defendant Richardson-Merrell Inc. In Support of Its Motion for Partial Summary Judgment Dismissing Plaintiffs' Claims for Fraud and Punitive Damages, February 5, 1982 at p. 42).

Plaintiffs' actions, to be sure, do not arise under federal law, as they do not assert a federally-created cause of action. Plaintiffs only urge that the federal Food, Drug and Cosmetic Act embodies the appropriate *standard of care* to be employed by the Ohio Court in determining if Merrell has been negligent, or if Bendectin is a defective product.

This principle of law regarding negligence *per se* has long been adopted by the courts in Ohio, and is indeed the

majority rule. W. Prosser, *Law of Torts*, § 36 (4th ed. 1971); *Restatement (Second) of Torts*, §§ 285, 286, 288B; and 39 O. Jur2d Negligence §§ 43-44 (1959).

In a recent Pennsylvania case, the United States Court of Appeals for the Third Circuit, in applying Pennsylvania law that is nearly identical to the law of Ohio on negligence *per se*, held as follows:

> "Under Pennsylvania law, the violation of a governmental safety regulation constitutes negligence per se" if the regulation "was, in part, intended to protect the interest of another as an individual [and] the interest of the plaintiff which was invaded . . . was one which the act intended to protect. Astra cannot seriously dispute that section 130.35 [of the Code of Federal Regulations implementing provisions of the Food, Drug and Cosmetic Act] was promulgated to protect individuals such as Harrikah Stanton from precisely the type of harm that here occurred—an unexpected adverse reaction to Xylocaine. It thus would appear that Astra's failure to file the reports constituted negligence per se.

Stanton v. *Astra Pharmaceutical Products, Inc.*, Nos. 92-3364 and 82-3380 (3d Cir., Sept. 26, 1983, Slip Op. at 21-22) (citations omitted) (Exhibit C).

In summary, plaintiffs' claim that Merrell's violations of the Food, Drug and Cosmetic Act constitute negligence *per se* does not give rise to federal question jurisdiction under 28 U.S.C. § 1331. In the absence of federal question jurisdiction, there simply is no basis for removal under 28 U.S.C. § 1441.

Article III Courts have limited jurisdiction. In the absence of original subject matter jurisdiction in these cases, removal is improvident.

B. *There is no other legally cognizable grounds for removal.*

Defendant could contend that jurisdiction of this Court could be based on 28 U.S.C. § 1332. This argument, too, must fail. In *Pack* v. *Rich Terminal Company,* 502 F.Supp. 58 (S.D. Ohio 1980), Judge Spiegel held that if a defendant is a citizen of a state, removal from state court is improper.

Ohio is Merrell's principal place of business. Merrell is a corporate citizen of Ohio. Removal, therefore, is inappropriate under 28 U.S.C. § 1441(b).

After a careful review of the United States Code to discern any other bases for the exercise of jurisdiction by federal courts under the circumstances of this case, plaintiffs can find no colorable basis for the exercise of jurisdiction by an Article III Court.

C. *The cases should be remanded to state court.*

In the absence of original jurisdiction in the federal courts, there simply is no basis for removal. The cases, therefore, should be remanded to state court. Finally, plaintiffs are entitled to the payment of costs and disbursements incurred because of these removal proceedings.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 14 day of October, 1983, a copy of the foregoing was hand-delivered to Frank C. Woodside, III, Esq., Dinsmore & Shohl, 2100 Fountain Square Plaza, 511 Walnut Street, Cincinnati, Ohio 45202.

/s/ JEROME L. SKINNER
Jerome L. Skinner

APPENDIX B

§ 3715.64 Misbranded drug.

(A) A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:

(1) Its labeling is false or misleading in any particular.

(2) It is in package form and does not bear a label containing:

(a) In clearly legible form the name and place of business of the manufacturer, packer, or distributor;

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; but reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the director of agriculture.

(3) It is a dangerous drug and does not bear a label containing in clearly legible form the name and place of business of the manufacturer of the finished dosage form and, if different, the packer or distributor.

(4) It is a dangerous drug in finished solid oral dosage form, unless it has clearly and prominently marked or imprinted on it an individual symbol, company name, national drug code or other number, words, letters, or any combination thereof, identifying the drug and its manufacturer or distributor. This requirement does not apply to drugs that are compounded by a registered pharmacist. The manufacturer or distributor of each such drug shall make available to the state board of pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor. The board of pharmacy shall provide this information to all poison control centers in the state. Upon application by a manufacturer or distributor, the board may exempt a drug from the requirements of this division

on the grounds that marking or imprinting such drugs is not feasible because of its size, texture, or other unique characteristic.

(5) Any word, statement, or other information required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices, in the labeling, and in such terms as to render it likely to be read and understood by the ordinary individual under customery conditions of purchase and use.

(6) It is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, cabromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative has been found by the director to be, and by regulations proposed by the director and adopted by the public health council designated as, habit forming, unless its label bears the name and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(7) It is a drug and it is not designated solely by a name recognized in an official compendium unless its label bears:

(a) The common or usual name of the drug, if any;

(b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanalid, acetophenetidin, aminopyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis flucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any

derivative or prepartion of any such substances, contained therein; but to the extent that compliance with these requirements is impracticable, exemptions shall be established by regulations proposed by the director and adopted by the public health council.

(8) Its labeling does not bear:

(a) Adequate directions for use;

(b) Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary to the protection of users;

(c) Where compliance with any requirements of division (A)(8)(a) of this section, as applied to any drug or device, is not necessary for the protection of the public health, the director shall propose and the public health council shall adopt regulations exempting such drug or device from such requirements.

(9) It purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein, but the method of packing may be modified with the consent of the director. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States pharmacopoeia.

(10) It has been found by the director to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as required by regulations proposed by the director

and adopted by the public health council as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the director has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body has failed within a reasonable time to prescribe such requirements.

(11)(a) It is a drug and its container is so made, formed, or filled as to be misleading.

(b) It is an imitation of another drug.

(c) It is offered for sale under the name of another drug.

(d) The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, is neither the brand or drug prescribed nor a generically equivalent drug.

(12) It is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(13) It is a drug intended for use by man which:

(a) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a physician, dentist, veterinarian, or person licensed to prescribe any drug which, under the federal act, federal narcotic law, as defined in section 4729.02 of the Revised Code, and under sections 3715.01 to 3715.75, or Chapter 3719, of the Revised Code, may be dispensed only upon a prescription;

(b) Is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act" to use under professional supervision by a physician, dentist, or veterinarian, unless it is dispensed only:

(i) Upon a written prescription of a physician, dentist, or veterinarian;

(ii) Upon the oral prescription of a physician, dentist, or veterinarian which is reduced promptly to writing by the pharmacist;

(iii) By refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is promptly reduced to writing by the pharmacist.

(B) Any drug dispensed by filling or refilling a written or oral prescription of a physician, dentist, veterinarian, or person licensed to prescribe any drug which, under the federal act, federal narcotic law, as defined in section 4729.02 of the Revised Code, or under sections 3715.01 to 3715.75, or Chapter 3719, of the Revised Code, may be dispensed only upon a prescription shall be exempt from the requirements of this section except divisions (A)(1) and (11) of this section if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in the prescription. Unless the prescription directions prohibit labeling, the label shall include the brand name of the drug dispensed. If the drug dispensed has no brand name, the generic name and the distributor of the finished dosage form shall be included. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

•HISTORY: 139 v. 135. Eff 1-1-82.

The effective date provisions of § 3 of HB 135 (139 v —) read as follows:

SECTION 3. The requirement of division (A)(4) of section 3715.64 of the Revised Code that manufacturers and distributors of dangerous drugs in finished solid oral dosage form make available to the State Board of Pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor shall not take effect until January 1, 1982. No criminal penalty shall be imposed for the manufacture, sale, or delivery, or holding or offering for sale of any misbranded drug as defined in division (A) the manufacture, sale, or delivery, or holding or offering (4) of section 3715.64 of the Revised Code unless such drug was manufactured on or after July 1, 1982.

§ 3715.68 False advertising.

(A) An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular.

(B) For the purpose of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, tuberculosis, tumors, typhoid, uremia, venereal disease, is also false, except that no advertisement not in violation of division (A) of this section is false under the division if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary profession, or appears only in the scientific periodicals of these professions; provided, that whenever the director of agriculture determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the director shall propose regulations for adoption by the pub-

lic health council authorizing the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the director may deem necessary in the interests of public health; provided, that this division shall not be construed as indicating that self-medication for diseases other than those named in this section is safe or efficacious.

•HISTORY: 138 v H 965. Eff 4-9-81.

§ 3715.52 Prohibitions.

The following acts and causing them are prohibited:

(A) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;

(B) The adulteration or misbranding of any food, drug, device, or cosmetic;

(C) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;

(D) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code;

(E) The dissemination of any false advertisement;

(F) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 3715.70 of the Revised Code;

(G) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in this state from whom he received in good faith the food, drug, device, or cosmetic;

(H) The removal or disposal of a detained or embargoed article in violation of section 3715.55 of the Revised Code;

(I) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

(J) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under sections 3715.52 to 3715.72 of the Revised Code.

(K) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that any application with respect to such drug is effective under section 3715.65 of the Revised Code or that such drug complies with the provisions of such section;

(L) The sale, offering for sale, giving away, or delivery at retail or to the consumer without a prescription from a physician, veterinarian, or dentist of any drug which under federal or Ohio law can be sold only on prescription.

(M) The using by any person to his own advantage, or revealing, other than to the director of agriculture or to the courts when relevant in any judicial proceeding under sections 3715.52 to 3715.72 of the Revised Code, any information acquired under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, concerning any information which is a trade secret is entitled to protection;

(N) The issuance by the manufacturer, packer, or distributor of a dangerous drug of any advertisements, catalogues, or price lists, except those lists specifically designed for disseminating price change information, that do not contain in clearly legible form the name and place of busi-

ness of the manufacturer who mixed the final ingredients and if different, the manufacturer who produced the drug in its finished dosage form and, if different, the packer or distributor.

HISTORY: 127 v 819 (Eff 9-13-57); 129 v 582 (799) (Eff 1-10-61); 137 v S 45. Eff 1-1-78.

The effective date of S 45 is set by section 3 of the act.

Cross-References to Related Sections

Penalty, RC § 3715.99(D).

Applicability of RC §§ 3715.52 to 3715.71 to the sale of shell eggs when not in conflict with RC §§ 925.02 to 925.07.1, RC §§ 925.02.

Pharmacists; disciplinary action by state board of pharmacy for willful violation of RC §§ 3715.52 to 3715.72, RC § 4729.16.

See RC §§ 3715.01, 3715.52, 3715.54-3715.57, 3715.59, 3715.60, 3715.63-3715.71 which refer to RC §§ 2715.52 to 3715.72.

See RC §§ 3715.01, 3715.53, 3715.54, 3715.99 which refer to this section.

Ohio Administrative Code

Display of placard. OAC 901:3-23-02.

Comparative Legislation

Adulteration of food:

Cal.—Health & Safety Code §§ 26520 et seq
Fla.—Stat. Ann. § 500.10
Ill.—Ann. Stat. ch. 56½, § 506
Ind.—Code § 16-1-29-2 et seq
Ky.—Rev. Stat. Ann. § 217.025

Mich.—Comp. Laws Ann. § 289.716
N.Y.—Agric. & Mkts. Law § 198 et seq
Pa.—Stat. Ann. tit. 31, § 1 et seq

Misbranding food and drugs:

Cal.—Health & Safety Code §§ 26550, 26630
Fla.—Stat. Ann. §§ 500.11, 500.15
Ill.—Ann. Stat. ch. 56½, § 506
Ind.—Code § 16-1-29-7 et seq, 16-1-30-5 et seq
Ky.—Rev. Stat. Ann. § 217.035 and 217.065
Mich.—Comp. Laws Ann. § 289.717
N.Y.—Agric. & Mkts. Law § 201
Pa.—Stat. Ann. tit. 31, § 1 et seq

Research Aids

Adulteration and misbranding:

O-Jur2d: Drugs §§ 11, 14; Food §§ 10, 14; Wts & M § 20
Am-Jur2d: Food § 21-26

Civil liability; practice and procedure:

O-Jur2d: Food §§ 52, 57
Am-Jur8d: Food §§ 84 et seq

Criminal liability; practice and procedure:

O-Jur2d: Food § 43
Am-Jur2d: Food § 74 et seq

ALR

Adulterated: construction and application of Federal Food, Drug, and Cosmetic Act § 402(a)(3) as to food deemed "adulterated," if it is filthy or the like, or unfit for food. 45 ALR2d 861.

Law Review

Advertising of food and drugs: concealing a truth, hinting a lie. Comment: Barry S. Donner. 8 Akron LRev 456 (1975).

Consumer protection in Ohio against false advertising and deceptive practices. James W. Carpenter, 32 OSLJ 1 (1971).

Products liability—the test of consumer expectation for "natural" defects in food products. Note. Charles Robert Janes. 37 OSLJ 634 (1976).

Reasonable certainty of no harm: reviving the safety standard for food additives, color additives, and animal drugs. Daryl M. Freedman, 7 EcologyLQ 245 (1978) .

The product liability of manufacturers: an understanding and exploration. Donald M. Jenkins. 4 AkronLRev 135 (1971).

Unwanted pregnancy and the pill—the question of liability of the manufacturer. Note. James M. Bordicks. 41 CinLRev 335 (1972).